



Welcome to the EndoNET Christmas Newsletter, providing trial updates, sharing top tips on good practice, and wishing you all the best for the festive period.

Recruitment has been steady over the last quarter and we have now randomised 144 patients with 32 teams open to recruitment. It was great to see Torbay and Yeovil – two of our newer teams - recruit well in the last quarter and Rotherham have also recruited their first patients.

It was sad to see POETIC-A close to registration, the team has been very supportive of EndoNET and our efforts to co-enrol to both studies. This leaves EndoNET as one of the largest UK randomised control trials currently active in the neoadjuvant endocrine therapy space and we need to make this trial a success to benefit women with breast cancer.

EndoNET Recruitment Championship

We asked each team to recruit x2 patients between 01Sep2024 and 30Nov2024 and 7 teams reached that target. **Torbay** led the way with a fantastic x5 recruits followed by **Yeovil** and **Churchill** with x4 and Basildon, Nottingham, Rotherham and Southampton all recruiting x2. Santa will be delivering some sweet treats to the winners in time for Christmas. Ho ho ho!

Next quarter we'll be rewarding the 5 teams that most improve recruitment between 01Dec2024 and 31Mar2025. You must recruit at least x2 to be eligible for a prize.

Substantial Amendment Update

Protocol V4.0 is **LIVE!**

The amendment was greenlit on 15Nov2024 and includes:

- Changing to one primary (surgical) outcome.
- Simplified and wider eligibility criteria.
- Improved patient facing documents including the PIS and a new animation video.
- Updated trial processes to make the study easier to run.

We've met most teams for refresher SIVs to introduce the protocol changes but please email endonet@nds.ox.ac.uk if you would like additional training or to discuss further.

Site Team	Recruitment Sep-Nov 2024	Total
Basildon	2	20
Churchill	4	18
Southampton	2	16
Castle Hill	0	11
Southend	0	10
Royal Devon & Exeter	0	10
Whiston	0	9
Torbay	5	6
Royal Hampshire	0	6
Yeovil	4	5
Nottingham City	2	5
Cumberland Infirmary	0	4
St Albans	0	4
Rotherham	2	3
Southmead	0	3
RAEI	1	3
Glenfield	0	3
Aberdeen Royal	0	2
Belfast City	0	2
Barnsley	0	2
Hairmyres	0	1
Llandough	0	1
Grand Total	22	144

* The 9 sites yet to recruit are not included in the recruitment table.



QRI

Patient Interviews

If you approach a patient for EndoNET who **declines participation**, please ask them if they would participate in an interview about their experience of considering EndoNET.

Several women interviewed have reported **being pleased to be able to still contribute to research** by participating in an interview.

Women can be offered the opportunity to take part in an interview after they have declined participation in EndoNET – this can be helpful if you have concerns about overwhelming them with information prior to them making their participation decision.

Audio-recordings of recruitment discussions

Does your site have a QRI audio-recorder? If so, please consider using it to record any discussions you have with patients about EndoNET. Verbal consent can be sought for this initially, followed by written OR telephone consent.

Audio-recording recruitment conversations is incredibly important to help us to provide training and support to all recruiters. All data collected are anonymised. Documents needed to inform and consent a patient for either the interviews and/or audio-recordings are the QRI PIS and Consent Form: EndoNET_QRIOnly_PIS_V3.0_21Aug2024 and EndoNET_Only-QRI_ICF_V2.0_10Jun2022.

If you have any questions, think you may have a patient to invite for an interview, or would like to receive an audio-recorder, please do not hesitate to contact Nicola Farrar: Nicola.farrar@bristol.ac.uk or 0117 455 1592.

Pre-Trial Endocrine Prescription

The updated eligibility criteria allows patients to start endocrine treatment up to 14 days prior to randomisation. Any AI prescription prior to randomisation should be a standard prescription. If the patient is randomised they will then move onto a trial-specific prescription.

Withdrawals

Please do not withdraw patients from the trial just because their clinical plan changes. EndoNET is a pragmatic trial and the primary analysis will be on an intention to treat basis. Therefore patients should not be withdrawn if the clinical plan changes even if, for example, it is subsequently apparent that a patient requires chemotherapy or surgery earlier or later than expected. This will ensure that the analysis is conducted in the scientifically current way and that we don't lose data unnecessarily. As a pragmatic trial, we are cognisant of the real world environment in which these patients are treated and, of course, remain respectful of the patient's wishes at all times.

NICE Nutritional Guidance

Lifestyle recommendations for the management of early and locally advanced breast cancer diagnosis and management can be found on the NICE website here: [Recommendations | Early and locally advanced breast cancer: diagnosis and management | Guidance | NICE](#)

It includes guidance on promoting a healthier lifestyle and dietary recommendations to support the patient whilst on treatment.

Delegation Log

Please keep your delegation logs up-to-date so that we can ensure that database access is assigned appropriately. Delegated staff should not perform any trial-related activity until the PI has signed the delegation log.

